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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,776	08/05/2003	Frederick G. St. Goar	17315-002001	1704
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EXAMINER				
BACHMAN, LINDSEY MICHELLE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,776

Applicant(s)

ST. GOAR ET AL.

Examiner

LINDSEY BACHMAN

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-29-08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,10-12,14-18,43 and 51-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,10-12,14-18,43 and 51-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicant's amendments filed on 18 December 2007 and 29 February 2008.

Claim Objections

Claims 51 and 52 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 43 requires that the anchor is placed directly on the annulus, while Claims 51 and 52 only require that the anchor is on or near the annulus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 8, 10, 12, 14-18, and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz, et al. (US Patent 6,269,819) in view of Kuehn et al. (US Patent 6,165,183).

Claim 1, 62, 65: Oz'819 discloses a device for modifying a heart valve to reduce regurgitation that includes a catheter (column 6, lines 29-34) for advancement through a patient's vasculature (column 8, lines 19-21), a stabilization structure (column 2, lines 33-53), and a supporting structure (column 2, lines 47-54) that is adapted for deployment on the annulus (column 5, lines 36-45). The structure moves between a delivery configuration and a deployed configuration (column 6, line 61 to column 7, line 2).

Claims 8 and 10: Oz'819 discloses that the supporting structure is a staple (column 6, lines 23-42 and column 5, lines 35-56).

Claim 12: Oz'819 discloses that the supporting structure is configured for deployment over the annulus (column 8, lines 19-30).

Claim 14: Oz'819 discloses that the catheter is configured to extend into the heart from a femoral venous location (column 8, lines 19-30).

Claim 15: Oz'819 discloses that the catheter is configured to extend across an inter-atrial septum of the heart (column 8, lines 19-30).

Claim 16: Oz'819 discloses that the valve is a mitral valve and the supporting structure modifies the annulus of a mitral valve (column 2, lines 20-22 and column 6, lines 61 to column 7, line 2).

Claim 17: Oz'819 discloses a guide catheter configured for advancement through a patient's vasculature from a remote access point into the heart (column 8, lines 19-30) and that the catheter and supporting structure are positionable through the guide catheter (column 8, lines 19-30).

Claim 18: Oz'819 discloses a supporting structure that is capable of tightening the annulus (column 4, lines 26-31 and Figures 24-25).

Claim 63: The stabilization structure disclosed by Oz'819 is removably attached to the catheter because it is slidable through the catheter.

Claim 64: Oz'819 discloses multiple staples that are coupled with the grasper. At least one of the staples is a wire that engages the cardiac structure (see Figure 11, 12).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 1, in further view of O'Connor, et al. (US Patent, 5,450,860).

Oz'819 teaches the limitations of Claim 11, except for circumferentially shortening the annulus.

O'Connor'860 teaches that it is beneficial to circumferentially shorten the annulus with the use of supporting structures (40) because the structures can be hidden between the plicated folds that are created when the annulus is shortened. This decreases the likelihood that the structures will cause irritation or loosen. Further, shortening the annulus is known to reduce mitral regurgitation (column 8, lines 5-28). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Oz'819 with the device taught by O'Connor'860 because

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circumferentially shortening the annulus reduces mitral regurgitation and creates plications which hide the support the structure and protect it from becoming loosened.

Claims 43, 51, 53-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (US Patent 5,593,424) in further view of Kuehn et al. (US Patent 6,165,183).

Claim 43: Northrup'424 teaches a method of modifying a heart valve (column 1, lines 8-12) that includes placing anchors (10) directly on the annulus (see Figures 2-4 and column 5, lines 17-48), coupling a filament to the anchors (column 5, line 59 to column 6, line 8) and tightening the filament to modify the annulus and reduce regurgitation (column 6, lines 3-8).

Northrup'424 does not teach a method of delivering the anchors.

Kuehn'183 teaches that it is known to percutaneously (column 5, lines 38-42 and column 13, lines 19-36) deliver anchors (132) attached to filaments (120) to the heart to aid in an annuloplasty procedure because this is less invasive and poses less risk for the patient. It would have been obvious to one skilled in the art at the time the invention was made to perform the method taught by Northrup'424 percutaneously, as taught by Kuehn'183 because it poses less risk to the health of the patient than a more invasive procedure.

Claim 51: Northrup'424 teaches that the anchors contain a suture (column 5, line 17 to column 6, line 8).

Claim 53: Northrup'424 teaches the invention substantially as claimed.

Northrup'424 does not teach extending the catheter into the heart from a femoral venous location.

Kuehn'183 teaches advancing the catheter from a femoral venous location because this is a well-known, large artery that leads to the heart and can be used to access with the heart with relative ease (column 13, lines 27-36). It would have been obvious to access the heart via the femoral artery as taught by Kuehn'183 when performing the procedure taught by Northrup'424 because this is a well-known and large artery that leads with the heart with relative ease.

Claim 54: Northrup'424 teaches the invention substantially as claimed.

Northrup'424 does not teach extending the catheter across the inter-atrial septum.

Kuehn'183 teaches extending the catheter across the inter-atrial septum in order to enter the left atrium of the heart (column 13, lines 27-36). It would be obvious to one skilled in the art at the time the invention was made to pass through the inter-atrial septum, as taught by Kuehn'183 in order to perform the method by Northrup'424 in order to access the left atrium of the heart via a non-invasive method.

Claim 55, 57, 58: Northrup'424 teaches that the method can be performed on a mitral valve (column 4, lines 34-46) and tightening the filament circumferentially tightens the annulus to reduce regurgitation in the mitral valve (column 5, lines 35-48).

Claim 56: Northrup'424 teaches the invention substantially as claimed.

Northrup'424 does not teach the use of a guide catheter.

Kuehn'183 discloses a guide catheter configured for advancement through a patient's vasculature from a remote access point into the heart (column 13 lines 27-36) and that the catheter and supporting structure are positionable through the guide catheter (column 8, lines 19-30) because guide catheters are well-known for guiding treatment devices through a patient's vasculature and into the heart. It would have been obvious to one skilled in the art at the time the invention was made to perform the method taught by Northrup'424 through a guide catheter as taught by Kuehn'183 because they are well known for use in accessing the heart.

Claim 59, 60 and 61: Northrup'424 teaches that tightening the filament comprises circumferentially tightening the filament by plicating portions of the annulus (column 5, lines 16-45).

Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup'424 in view of Kuehn'183, as applied to Claim 43, in further view of Oz, et al. (US Patent 6,269,819).

Claim 52: Northrup'424 in view of Kuehn'183 teaches the invention substantially as claimed except for a staple.

Oz'819 teaches a staple (156) because they close the valve in a preferred way (column 6, lines 34-43). It would have been obvious to one skilled in the art at the time the invention as made to modify the method taught by Northrup'424 in view of Kuehn'183 with the staple taught by Oz'819 because staples are well-known in the art and it would be obvious to one skilled in the art experiment with different types of fasteners.

Response to Arguments

Applicant's arguments filed 29 February 2008 with regard to independent claim 1, rejected by Oz'819 have been fully considered but they are not persuasive. Applicant argues that Oz'810 does not disclose a stabilization structure, however, as discussed in the rejection above, Oz'810 discloses a grasper which aids in stabilizing tissue.

Applicant's arguments filed 18 December 2007 with regard to independent claim 43, rejected by Northrup'424 in view of Oz'810 are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/L. B./
Examiner, Art Unit 3734